Ministry for the Environment
Manatū Mō Te Taiao

Te whakapiki i ō mātou waeture GMO mō te rangahau taiwhanga pūtaiao me te rongoā koiora

Improving our GMO regulations for laboratory and biomedical research

A snapshot of the consultation and FAQs

Proposed changes to Aotearoa New Zealand's GMO regulations

Genetic modification and genetically modified organisms (GMOs) are primarily regulated in New Zealand under the Hazardous Substances and New Organisms Act 1996 (HSNO Act), its regulations, and related standards. Genetic modification, as it is generally understood, is the modification of an organism's genetic makeup (such as its DNA) resulting in the creation of a GMO.

Genetic modification is used in many fields, including medicine, horticulture, agriculture, food production and industrial manufacturing. By altering gene function and expression, genetic modification enables gene therapies to treat diseases, the development of plants resistant to pest species and the production of useful enzymes, hormones and vaccines.

The challenge

Feedback from the New Zealand research community suggests the regulatory settings for GMOs could be improved so that laboratory and biomedical research can have a greater positive impact for New Zealanders.

This consultation

The policies proposed in the consultation document aim to help researchers, universities and businesses by reducing unnecessary regulatory barriers to laboratory and biomedical research that uses GMOs.

The proposed policies cover the regulations and controls for research conducted in laboratory settings, the assessment and approval for biomedical therapies, and making the legislation and regulations more up to date and future proof.

These proposals are primarily limited to the regulatory provisions for biomedical therapies and research undertaken in laboratory settings, and they do not cover the provisions for field trials, conditional releases and full releases of GMOs.

Proposals

Below are summaries of the 10 policy changes we are proposing to make to the regulatory settings for GMOs.

Proposal 1: Introduce a risk-tiering framework for laboratory research

This proposal would see the introduction of a risk-tiering framework modelled on the framework used under Australian regulations. Under the proposed framework, individuals and groups could import and produce low-risk GMOs without requiring Environmental Protection Authority (EPA) approval if their research falls within the criteria of a risk tier and they can meet that risk tier's requirements.

There would be three risk tiers under the proposed framework, ranging from research presenting no to very low risk to the environment and people, to research presenting low to medium risk to the environment and people. For each risk tier, several assessment and facility requirements would need to be met, proportionate to the risk level of each risk tier.

This framework would reduce administrative work required of researchers to gain approval for low-risk research and lower start-up costs for new organisations and startups. It would also remove the requirement for EPA assessment and approval for medicines using organisms under the lowest risk tier (for example, personalised cancer therapies).

Proposal 2: Reduce the assessment and approval requirements for medicines that are, or contain, new organisms (which includes GMOs)

We are proposing three changes to the assessment and approval requirements for biomedical therapies under the HSNO Act. These changes aim to make the process faster and more efficient by:

- streamlining the assessment process by removing its first evaluation stage
- introducing an alternative assessment pathway for biomedical therapies using new organisms that are unlikely to make their way into the environment
- allowing medical devices that use new organisms to be rapidly assessed by the EPA.

These changes would result in several benefits, such as:

- saving researchers time in preparing applications
- cutting down on the time and resources the EPA needs to review applications
- speeding up the approval process and reducing costs for medical devices that use new organisms.

Proposal 3: Replace current record-keeping requirements

We're proposing changes to how records are kept for new organisms, including genetically modified organisms. Here's what this would look like under our proposal:

- Any new organisms, or their containers, would need to be clearly marked to show they contain new organisms.
- A tracking system would need to be in place to monitor new organisms in facilities operated at Physical Containment Level 3, and for animals that could escape their enclosures.

The aim of these changes is to reduce the paperwork for researchers. They would also minimise the risk of accidental cross-contamination and mean it can be confirmed that no organisms with the ability to do so have escaped.

Proposal 4: Adjust internal audit frequency to be proportionate to risk

We're proposing to reduce the frequency of internal audits (that is, audits carried out by facility operators) for laboratories operated at the least stringent level, from every six months to a minimum of every 12 months.

The frequency of internal audits and external inspections for all other facilities would remain unchanged.

Reducing the frequency of these internal audits would free up researcher time, lower the costs associated with these audits, and free up time for biosafety officers to concentrate on areas of higher risk.

Proposal 5: Adjust the requirements for the movement of new organisms to be proportionate to risk

Like Proposal 4, the changes we're suggesting here would modify the rules for transferring new organisms between laboratories, making the rules more risk proportionate.

We're proposing to remove the current requirement that the Ministry for Primary Industries (MPI) must first give permission for a transfer between laboratories. This would apply to laboratories that fall under risk tiers 1 and 2 of the proposed risk-tiering framework under Proposal 1.

Under these changes, transfers would be allowed as long as the new organisms are properly packaged, labelled, and transported. For laboratories covered by risk tier 2, the transfer would also need to be recorded.

Proposal 6: Reduce regulatory requirements for the use of eukaryotic somatic cells

Under this proposal, eukaryotic somatic cells would be included under risk tier 1, the least stringent tier of the proposed risk-tiering framework under Proposal 1.

Eukaryotic cells are cells of eukaryotes, which include humans, animals, plants, fungi and many unicellular organisms, but that do not include bacteria and archaea. Somatic cells are cells that are non-heritable and that can't be passed down to offspring, unlike reproductive cells.

This change would enable researchers to work with these very-low-risk cells without having to meet the requirements imposed for higher-risk organisms. Furthermore, medical treatments using these cells would only need approval from Medsafe, rather than also needing to be reviewed and approved by the EPA.

Proposal 7: Clarify the regulatory status of certain biotechnologies

This proposal would see the regulatory status of three biotechnologies clarified under the HSNO Act. These technologies are:

- the introduction of RNA into an organism (for example, mRNA vaccines),
- the introduction of DNA into an organism (for example, DNA vaccines, which are an advancing technology)
- epigenetic modifications (which are changes to the expression of genes without changing the underlying genetic sequence).

According to the conditions that would be placed on them, the use of these three biotechnologies would not result in modifications to the genetic makeup of an organism and would not include gene-editing techniques in any form.

It is likely that clarifying the status of these biotechnologies under regulations would provide certainty and clarity to researchers, and in doing so lead to their increased use in research and in biomedical therapies in future.

Proposal 8: Reduce assessment requirements for low-risk fermentation

This proposal would link fermentation approval with the risk-tiering framework outlined in Proposal 1. Under the framework, research that meets the criteria for risk tiers 1 to 3, EPA assessment and approval requirements would be replaced with assessment by an accredited biosafety committee.

Additionally, depending on the research in question, fermentation meeting the criteria of risk tiers 1 to 3 would require a containment facility operating at either PC1 or PC2.

This change would reduce the administrative burden on researchers and organisations and would ensure that fermentation is proportionately regulated.

Proposal 9: Maintain or adjust the approach to standards for containment facilities

This proposal outlines three potential options for containment facility standards. These standards outline the controls that are required within containment facilities for new organisms (which include GMOs).

The first option is to retain the status quo of prescriptive standards. A benefit of this option is that standards for containment facilities and transitional facilities would have the same broad approach. Small organisations with containment facilities may also find it easier to implement measures that meet prescriptive controls, compared with the extra effort that may be required to meet outcome-based controls.

The second option is outcome-based standards (that is, standards specifying outcome-based controls). These controls specify an outcome that must be achieved, for instance '*the containment facility must be designed, constructed, managed and maintained to prevent new organisms from escaping*', but allow facility operators to choose how it is achieved. Several guides would be published, outlining how these outcomes could be effectively achieved. The potential benefit of outcome-based controls is that they allow researchers to use control measures in their containment facilities that may be more appropriate to the specific organism and research in question, relative to prescriptive controls.

The third option is a hybrid approach which would combine aspects of the status quo and outcome-based standards. Under this approach, outcome-based standards would be specified for containment facilities that hold new organisms, as under the outcome-based standards option outlined above. In addition, default measures that would meet these outcome-based controls would be specified (these would likely be the same as those currently under the existing standards). Under this approach, facility operators could either choose to implement the default measures that would meet the outcome-based controls or could implement other non-default measures that would also meet those controls.

Proposal 10: Require regular reviews of regulatory settings

This proposal would require the regulatory settings for GMOs to be reviewed by the Ministry for the Environment every five years. This review would encompass horizon-scanning for new biotechnologies (and the regulatory settings appropriate for these) and could also include a summary of relevant changes to regulations in other international jurisdictions.

A written report of each review, including any recommendations for changes to the regulatory settings, would then be provided to the Minister for the Environment.

This change would help make sure that our regulations don't become outdated or unsuitable and would encourage proactive planning for future developments in biotechnology.

Frequently asked questions

Do these proposals cover the regulatory provisions for field trials or releases of GMOs into the environment?

No. None of the proposals cover the provisions for field trials, conditional releases or full releases under the Hazardous Substances and New Organisms Act 1996 (HSNO Act). The exception to this is the provisions for medicines that are, or contain, new organisms that are defined as a "release" under the HSNO Act.

Will medicines and biomedical therapies that are, or contain, new organisms continue to require assessment and approval prior to use?

Yes. All medicines and biomedical therapies will continue to require assessment and approval by Medsafe prior to any use in clinical trials and in clinical settings, as required under the Medicines Act 1981. In addition, those medicines and biomedical therapies that meet the criteria to also be assessed under the HSNO Act would continue to require assessment by the Environmental Protection Authority (EPA).

Will the proposals for RNA biotechnologies (Proposal 8) change the requirements for mRNA therapeutics under the HSNO Act?

No. The new organism/GMO provisions of the HSNO Act do not apply to mRNA therapeutics. This is because mRNA molecules do not meet the definition of an "organism". Read more about the EPA's February 2021 determination.

Proposal 8 would clarify under legislation the regulatory status of RNA technologies and two other biotechnologies (DNA biotechnologies and epigenetics), based on these biotechnologies not resulting in GMOs. This is intended to provide certainty and clarity to researchers about the regulatory status of these biotechnologies under the HSNO Act.

Does that mean that no types of RNA biotechnology would be covered by the provisions of the HSNO Act?

No. Some RNA biotechnologies may be subject to assessment and approval requirements under the HSNO Act if they meet the criteria to be considered a hazardous substance. In these instances, these substances would require approval from the EPA before they could be imported into or manufactured in New Zealand.

Are these proposals changing the regulations for food that contains GMOs or ingredients derived from GMOs?

No. The regulatory requirements for food that contain GMOs, or ingredients derived from GMOs, come under the Food Standards Code, which are overseen by Food Standards Australia New Zealand (FSANZ). Read more about the Food Standards code and FSANZ.

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Help shape the regulatory settings for GMOs

For full details on the proposals, the problems we are trying to solve and the options we have considered, see the full consultation document.

You can provide a submission through Citizen Space, our consultation hub, by either following the feedback form or by uploading your own written submission.

We would prefer that you don't email or post your submission to us as this makes our analysis more difficult. However, if you need to, mail your written submission to:

Biotechnology Policy
Ministry for the Environment
PO Box 10362
Wellington 6143.

If you are emailing your submission, send it to biomedicalreview@mfe.govt.nz.

Submissions close at 11.59pm on Friday 25 August 2023.

What happens next

This consultation starts on Monday 3 July 2023 and closes on Friday 25 August 2023.

The Government will consider the submissions and may refine the proposals based on feedback received. Following consultation and further policy development, the regulations will likely be in force (subject to Cabinet decisions) in 2025.

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